

REMARKS

Claim 18 has been amended to indicate that the claimed device is capable of making not only a positive or a negative call, but also an indeterminate call. This amendment is supported on page 13, line 22 through page 14, line 31 of the application as filed. Claim 26 has been canceled without prejudice. Claim 21 has also been amended to correct a typographical error replacing the word “Last” with the word “Late.” This corrected wording is supported on page 19 at line 16.

Rejection of Claims 18-23 and 26 under 35 U.S.C. § 112, ¶ 1 for New Matter

The Examiner has rejected claims 18-23 and 26 under 35 U.S.C. § 112, ¶ 1 as failing to comply with the written description requirement. The Examiner contends that claims 18-23 and 26 contain new matter based on an amendment to claim 18 in the response filed on December 28, 2006 in this application to add the phrase “by evaluating a function that depends on the first score and the second score as independent variables of the function.” Applicant respectfully traverses the Examiner’s rejection. The phrase “by evaluating a function that depends on the first score and the second score as independent variables of the function” is supported on at least page 13, line 22 through page 14, line 31 and page 20, lines 4-31 of the specification.

Page 13, line 22 through page 14, line 31 of the application as filed describes the calculation of a “composite *Score*” using scores from a plurality of tests that are described on page 15, line 1 to page 20, line 1. The composite *Score* is used to determine whether the sample is positive, negative, or indeterminate for the presence of a nucleic acid. On page 13, lines 22-24 of the specification it is stated that “[a] further approach to automated analysis of real-time nucleic acid amplification is to use algorithms that employ one or more tests to

obtain an aggregate score that defines, with higher accuracy and robustness, whether the sample is positive, negative, or indeterminate.” As also stated on page 14, lines 25-26, individual tests can be used to provide the “composite *Score*.” Thus, the automated analysis used by the claimed device uses algorithms that employ tests to obtain a composite *Score* used to determine whether the sample is positive, negative, or indeterminate for the presence of a nucleic acid.

The formula for determining a composite *Score* is shown on line 1 of page 14. Clearly, a “composite *Score*” is generated by “evaluating a function that depends on the first score and the second score as independent variables of the function” because the formula shown on line 1 of page 14 is a function in which the first score (T_1) and the second score (T_2) are independent variables (*i.e.*, independent tests) of the function. As stated on page 13, lines 29-30, “each of the tests produce a score, T_1, T_2, \dots, T_n .” Accordingly, T_1, T_2, \dots, T_n are the test scores that are the independent variables of the function that is evaluated to determine whether a sample is positive, negative, or indeterminate for the presence of a nucleic acid.

MPEP § 2163.02 states that the “subject matter of the claim need not be described literally (*i.e.*, using the same terms or *in haec verba*) in order for the disclosure to satisfy the description requirement.” Also, MPEP § 2163.05 states that “each claim limitation must be expressly, implicitly, or inherently supported in the original disclosure.” Thus, under the MPEP and the case law cited in the MPEP, literal support is not required for claim limitations. Rather, patent claim limitations need to be *expressly, implicitly, or inherently* supported in the originally filed application. It is clear that the phrase indicating that a composite *Score* is generated by “evaluating a function that depends on the first score and the second score as independent variables of the function,” objected to by the Examiner as being new matter, is at least implicitly and inherently supported in the original disclosure.

The formula at the top of page 14 is a function used to generate a composite *Score* and the function depends on a first score (T_1) and a second score (T_2) as independent variables of the function. The composite *Score* is used to determine whether a sample is positive, negative, or indeterminate for the presence of a nucleic acid. Thus the phrase “evaluating a function that depends on the first score and the second score as independent variables of the function,” does not constitute new matter. Withdrawal of the rejection of claims 18-23 and 26 under 35 U.S.C. § 112, ¶ 1 is respectfully requested.

Rejection of Claims 18-23 and 26 under 35 U.S.C. § 112, ¶ 1 for Lack of Enablement

The Examiner has rejected claims 18-23 and 26 under 35 U.S.C. § 112, ¶ 1 as lacking enablement. The Examiner contends that the claims contain subject matter that was not described in the specification in such a way as to enable one skilled in the art to make and/or use the invention. The Examiner indicates that claim 18 recites a device for determining the *presence* of a nucleic acid in a sample comprising an instrument for temperature cycling, a fluorimeter, and a processor that determines whether a sample is *indeterminate* for the presence of a nucleic acid. The Examiner also indicates that if the function is designed to increase the number of correct calls in the unable-to-call region, one skilled in the art would still need to undergo undue experimentation to determine what is actually determinate so that sound scientific conclusions could be made on the sample. Applicant respectfully traverses the Examiner’s rejection. Claims 18-23 and 26 are enabled under 35 U.S.C. § 112, ¶ 1.

To respond to the Examiner’s first objection that claim 18 recites a device for determining the *presence* of a nucleic acid in a sample comprising an instrument for temperature cycling, a fluorimeter, and a processor that determines whether a sample is *indeterminate* for the presence of a nucleic acid, Applicant has amended claim 18 to indicate

that the claimed device is capable of making not only an indeterminate call, but is also capable of making a positive or a negative call. Claim 18, as amended in the present response addresses the Examiner's objection that the preamble and body of pending claim 18 are inconsistent.

The Examiner also indicates that if the function is designed to decrease the number of correct calls in the unable-to-call region, one skilled in the art would still need to undergo undue experimentation to determine what is actually determinate so that sound scientific conclusions could be made on the sample. Contrary to the Examiner's contention, the device decreases the number of correct calls in the unable-to-call region, and allows the skilled artisan to obtain scientific conclusions that are more sound because the device is designed to increase the accuracy of the information obtained. A method that decreases the number of true positive results that fall into an unable-to-call region necessarily increases the accuracy of the results that are obtained. In the specification, beginning on page 13 at line 21 and continuing through page 21, the application describes in great detail how the claimed device works and how algorithms are used to compute a Composite *Score* using a plurality of tests to determine whether a sample is positive, negative, or indeterminate for the presence of a nucleic acid. In the process of this determination, the claimed device decreases the number of positive results that fall into an unable-to-call region necessarily increasing the accuracy of the results obtained and the soundness of the scientific conclusions that can be made on the sample. Thus, the claimed invention is enabled under 35 U.S.C. § 112, ¶ 1. Withdrawal of the rejection of claims 18-23 and 26 under 35 U.S.C. § 112, ¶ 1 is respectfully requested.

Rejection of Claims 18-23 and 26 under 35 U.S.C. § 112, ¶ 2

The Examiner has rejected claims 18-23 and 26 under 35 U.S.C. § 112, ¶ 2 as being indefinite for failing to point out and distinctly claim the subject matter which

Applicant regards as the invention. The Applicant has amended claim 18, as discussed above, to address the Examiner's objection that the preamble and body of pending claim 18 are inconsistent. Withdrawal of the rejection of claims 18-23 and 26 under 35 U.S.C. § 112, ¶ 2 is respectfully requested.

Rejection of Claims 18-23 and 26 under 35 U.S.C. § 103(a)

The Examiner has also rejected claims 18-23 and 26 under 35 U.S.C. § 103(a) as being obvious over Witter (U.S. Patent No. 6,387,621; hereinafter the '621 patent) in view of Schork et al. (U.S. Patent No. 6,291,182; hereinafter the '182 patent) and Clark et al. (U.S. Patent No. 6,656,428; hereinafter the '428 patent). Applicant respectfully traverses the Examiner's rejection. Amended claims 18-23 and 26 are not obvious over the '621 patent in view of the '182 patent and the '428 patent.

It is well-established that in order for prior art references to establish a *prima facie* case of obviousness under 35 U.S.C. § 103, the references must teach or suggest all of the claim limitations ((MPEP 2134.03). Claim 18 has been amended to require that the processor is programmed "to evaluate the function that depends on the first score and the second score as independent variables of the function to determine whether the sample is indeterminate for the presence of the nucleic acid."

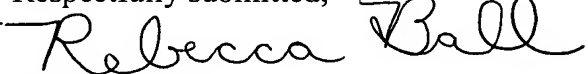
The Examiner is relying on the '428 patent to provide disclosure of a method used to determine whether a sample is indeterminate for the presence of a nucleic acid. The '428 patent uses a method that involves generation of a standard curve created prior to the assay measurement. In other words, the assay measurement is compared to data that preexist (*i.e.*, a standard curve) in contrast to the method described in the present application which involves assay measurements which in and of themselves are used to make positive, negative, or indeterminate calls. Further, as required by amended claim 18, an indeterminate call can

be made because the processor is programmed "to evaluate the function that depends on the first score and the second score as independent variables of the function to determine whether the sample is indeterminate for the presence of the nucleic acid." The '428 patent does not disclose evaluating a function that depends on *the first score and the second score as independent variables of the function to determine whether the sample is indeterminate* for the presence of the nucleic acid. A standard curve uses one independent variable rather than multiple independent variables. Thus, the '428 patent does not teach a function evaluated using multiple independent variables to determine whether a sample is indeterminate for the presence of a nucleic acid. None of the cited references teaches this claim limitation. Thus, the combination of the '621 patent, the '182 patent, and the '428 patent cited by the Examiner does not render the claims obvious because the reference combination does not teach all of the claim limitations. Withdrawal of the rejection of claims 18-23 and 26 under 35 U.S.C. § 103(a) over the '621 patent in view of the '182 patent and the '428 patent is respectfully requested.

CONCLUSION

The foregoing amendments and remarks are believed to fully respond to the Examiner's rejections. The amended claims are in condition for allowance. Applicant respectfully requests allowance of the claims, and passage of the application to issuance.

Respectfully submitted,



Rebecca L. Ball
Registration No. 46,535
Attorney for Applicant

(317) 231-7511
Indianapolis, Indiana 46204